

Appl No 10/626,282  
Amdt dated January 26, 2006  
Reply to Office Action of October 3, 2005

**Amendment to the Drawings**

The attached replacement sheets of drawings, Figures 1, 2A-2F, 3-4, 5A-5E, 6, 7A-7E, 8-10, 11A-11C, 12 and 13A-13D, include all of the requested actions from the examiner to eliminate copy machine marks and lighten the dark coloration of the drawings. No figures have been canceled and no figures have been amended except as stated above.

### **Remarks/Arguments**

This amendment is in response to the Office Action dated October 3, 2005.

Claims 1-4, 6-9 remain in this application. Claim 5 has been canceled. New claims 10 - 14 have been added to further define the present invention. Support for the claims are found throughout the specification. Support for claim 10 is found at Page 3, lines 6-9. Support for claims 11-13 is found in claim 2, and claim 5 as originally filed. Support for claim 14 is found at Page 5, lines 19-21. Support for claim 15 is found in the specification at Page 5, lines 1-3.

The objections to the Drawings have been overcome via the submission of replacement drawings. Acceptance by the Examiner is respectfully requested.

Applicants have submitted an additional Information Disclosure Statement for consideration by the Examiner.

Claims 1-9 have been rejected under 35 USC 103(a) over Svensson (US 4,306,705)

Applicant disagrees.

The present invention relates to a sterile connector formed of at least two parts, the connector and the coupling. Both the connector and the coupling use sterile sealing plugs to close off the sterile interior of the components from the outside environment.

The office action recognizes that the cited reference does not teach using sealing barrier plugs. Instead, it uses "valve 3, valve 44 or filters" to create a sterile barrier within the flow passage and that it would have been obvious to one of ordinary skill in the art to place sterile barriers such as filters in the flow passage of the Svensson valve in order to maintain sterility.

Applicants cannot find a reference to the use of filters in the reference as stated in the office action and asks that the specific passage be pointed for Applicants consideration. Even if the reference does suggest the use of "filters" that is not what is claimed by the present invention.

The sterile plugs of the present invention provide a strong and secure barrier against the outside environment from entering the sterile interior of the connector. Moreover, they are unique and quite different from what is taught or suggested by the reference. These plugs have a radial seal as can be easily appreciated by one of ordinary skill in the art. Such seals are strong and difficult to dislodge except when one deliberately means to do so, thereby providing a good assurance of sterility. The product of the reference uses a linear seal such as the valve 3. Such seals are difficult to maintain in a sterile condition and are easily dislodged.

The Examiner has cited no art that shows such a plug, and therefore provided no basis for concluding that it would have been obvious to somehow modify the reference to arrive at the claimed invention. No basis has been provided for any suggestion or motivation in the cited reference to modify it such that the present invention as claimed would be arrived at. See *In re Rouffet*, 47 U.S. P.Q.2d 1453, 1457-58 (Fed. Cir. 1998) ("To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the examiner to show a motivation to combine the references that create the case of obviousness. In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with knowledge of the claimed invention, would select the elements from the cited prior

art references for combination in the manner claimed."). No motivation has been provided as to why the skilled artisan would modify the valve of the reference by a sterile plug as claimed. It is well settled that to establish a *prima facie* case of obviousness, the prior art must teach or suggest all the limitations of a claim, there must exist a suggestion or motivation in the reference itself or as a matter of general knowledge to modify the reference, and there must be a reasonable expectation of success. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). Applicants respectfully submit that a *prima facie* case of obviousness has not been established in this instance.

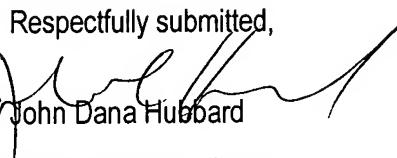
Additionally, the coupler also contains a stem that is capable of moving into and through the open port of the connector when assembled. This ensures that there is a sterile pathway through the device when used. It also helps to lock the components together making their accidental removal unlikely. The cited reference fails to teach or suggest this element as well. One of ordinary skill in the art would not have any suggestion or motivation to use such a stem from the teachings of the reference or as a matter of general knowledge to modify the reference. Applicants respectfully submit that a *prima facie* case of obviousness has not been established in this instance.

The office action states that the claims drawn to the size of the openings would have been within the skill of a worker in the art. The dimension in the claim is not a diameter as is believed to be assumed by the office action, but rather a depth ("dimension") suitable for containing one or more of such plugs within the depth of the same opening. This is so one can cause the two adjacent plugs to mate sealing their non-sterile surfaces between them and then to retain those plugs within the same opening. As such, it is believed these claims are unobvious to one of ordinary skill in the art and therefore in condition for allowance.

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Reconsideration and allowance of the remaining claims is respectfully requested in view of the foregoing amendment and remarks.

Respectfully submitted,



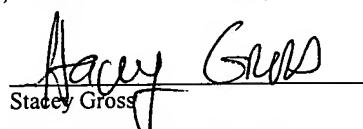
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The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on **January 26, 2006**.



Stacey Gross